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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/765,271	01/22/2001	Gil H. Choi	PB340P2C3	9691

22195 7590 05/19/2004

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EXAMINER	
DUFFY, PATRICIA ANN	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/765,271	CHOI ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on 2/6/04

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1, 18, 19, 22-84 is/are pending in the application.

4a) Of the above claim(s) 18, 19 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 22-84 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESPONSE TO AMENDMENT

The amendment and response filed 8-6-03 has been entered into the record. The amdendment to the sequence listing filed 2-6-04 has been entered. Claims 18, 19 and 22-84 are pending. Claims 1-17 and 20-21 are cancelled. Claims 22-85 are under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Election/Restrictions

This application contains claims 18 and 19 drawn to an invention nonelected with traverse in Paper received 1-28-03. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. At this time claim 55 has not been rendered allowable and as such rejoinder of claim 18 in view of *In re Ochiai*, 71 F3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and *In re Brouwer*, 77 F3d. 422, 37 USPQ 2d 1663 (Fed. Cir. 1996) is not appropriate at this time. Applicants are reminded that for rejoinder, the rejoined claim must depend or include all limitations from an allowable claim. Additionally, claim 19 is not drawn to a method of use of any claimed polynucleotide and therefore will not be rejoined at any point because it does not include all the limitations of any of the polynucleotide claims.

Rejections Withdrawn

The rejection of claim 9 under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in a way as to enable one skilled in the art to which it pertains, or with which it is most clearly connected, to make and/or use the invention is withdrawn based on cancellation of the claim.

The rejection of claims 1-9 and 13 under 35 USC 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn based on cancellation of the claims.

The rejection of claim 2 under 35 USC 102(b) as being anticipated by Birkett et al (US Patent No. 5,302,527) or Boehringer Mannheim 1991 Catalog or Stratagene 1991 Product Catalog is withdrawn in view of the cancellation of the claims.

The issues with regard to sequence compliance have been resolved and this objection is withdrawn.

Rejections Maintained

Claims 22-32, 55-65, 71-77 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons made of record for claims 1-9 and 13 in the Office Action Mailed 5-6-03.

Applicants argue that the amendment of the claims to recite "consisting of" obviates this issue. This is not persuasive and does not address the issue of variants, hybridizing variants etc. Applicants have not provided written description of variants. Applicants have provided but a single nucleic acid (SEQ ID NO:55), presumably encoding a polypeptide (SEQ ID NO:65). As such, there is no showing of possession of the claimed genus of variants. As set forth previously, the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1st "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January

5, 2001, see especially page 1106 3rd column). In the instant case, there is no reduction to practice of a representative number of species, no disclosure of relevant identifying characteristics or functional characteristics coupled with a known or disclosed correlation between function and structure. The claims as amended still do not meet the written description guidelines. There is no established correlation between structure and function. The function of the SP036 polypeptide encoding by the polynucleotide is not discussed nor disclosed by the specification. Clearly, one skilled in the art would recognized that in the absence of a correlation of structure and function, the disclosure of a single nucleic acid does not describe a genus unlinked by structure and function.

Claims 22-65, 71-77 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide consisting of SEQ IDNO:55, specific fragments thereof, vectors and host cells consisting of these, it does not reasonably provide enablement for an isolated polynucleotide comprising SEQ ID NO:55, or a nucleic acid sequence encoding an amino acid sequence comprising SEQ ID NO:56 or epitope bearing portions thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims is maintained for reasons made of record for claim 1-9 and 13 in the Office Action Mailed 5-6-03.

Applicants arguments have been carefully considered but are not persuasive. Applicants argue that the claims as amendment do not describe any undescribed sequences. This is not persuasive, there are no variants of the nucleic acid sequence or of the polypeptide sequence disclosed. There is no known or disclosed correlation between structure of the nucleic acid and function of the polypeptide. As such, the examiner maintains that the claims encompass undisclosed and undescribed sequences. Applicants argue that the polynucleotides can be used for the detection of Streptococci and as antigens for vaccines. This is not persuasive, the claims are not limited to those that

provide for the detection of Streptococci and Applicants have not provided any description of variants of the sequence which could be used as such. While a particular described nucleic acid sequence would be expected to hybridize to its homolog, nucleic acid sequences that differ in every third nucleotide (i.e. the encoding language of the claims) would not be expected to hybridize, because it is well established in the hybridization art that at least 15-20 identical consecutive nucleotides are required to form a stable hybrid. When every third nucleotide residue is a wobble position, one would not expect that this nucleic acid would hybridize as asserted. As to vaccines, the specification is devoid of any data indicating that an immune response is naturally generated to the polypeptide encoded by the polynucleic acid. Further, there is not a single piece of evidence that the immune response to such a polypeptide is protective. Protection is required by a vaccine. As such, polynucleic acids encoding polypeptides are not enabled. Applicants admit that they did not disclose the complete ORF and indicate that a more complete listing of the genome can be found in copending application 60/029,960. This does not address the issue. There is no evidence that Applicants were in possession of a polypeptide that is actually expressed by *Streptococcus pneumoniae*. Applicants argue that the polynucleotides have been modified for use as antigens. This again is not persuasive, there is no evidence that the polypeptide sequence is in fact an antigen from *Streptococcus pneumoniae*. Applicants indicate that the complete ORF is disclosed in Serial number 60/029,960. It is noted that this specification must meet the criteria, Applicants can not rely upon essential material in a prior application that is improperly incorporated by reference. Applicants have not provided a comparison of the two sequence in such a manner that unequivocally demonstrates possession of any full length open reading frame. Further, this argument does not provide evidence for the genus of nucleotides and polypeptides. Applicants are not enabled for their entire scope for reasons supra and already made of record.

New Rejections Based on Amendment

Claims 25, 55-65 and 81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 25, in line 2, there is an apparent misspelling of "polynucl otide". Correction is required.

As to claims 55-65, the claims recites "at least about" is prima facie indefinite because "at least" conveys an absolute lower level of 15 consecutive nucleotides whereas "about" provides for latitude below the recited 15. As such, the skilled artisan would not be readily apprised as to the metes and bounds of what is included or excluded by the claims.

As to claim 81, the claim is indefinite in the use of comprising language because it is in conflict with the closed language of the independent claim from which it depends.

New Rejections

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22-~~76~~ 84 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14, 21, 31,40, 50 and 55-76 of U.S. Patent No. 6,420,135. Although the conflicting claims are not identical, they are not patentably distinct from each other because residues 3053-4511 of claimed SEQ ID NO:94 of the '135 patent are identical to residues 1-2389 of SEQ ID NO:55 claimed herein. The disclosure of the larger sequence anticipated or renders obvious any subsequence because any subsequence can be used to detect the presence of *S. pneumoniae* DNA by hybridization. Since the nucleic acids are identical, the nucleic acid inherently encodes the identical polypeptide and as such, anticipate or render obvious any polypeptide and epitopic fragments thereof because these are useful for making antibodies to detect the presence of the pathogenic microorganism in a biological sample.

Claim 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 4547, 48, 49, 50, 51, 52, 53, 54, 55 and 56-65 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 35-47 of copending Application No. 09/765,272, all the claims of 10/158,844 or all the claims of US Publications 20020061545A1 and 20040029118A1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed nucleic acid encoding an epitope portion of the polypeptide of SEQ ID NO:66 comprising a portion of at least residues Ile 175- Asp 181 of SEQ ID NO:66 anticipates the invention claimed herein because residues 160-210 of SEQ ID NO: 56 recited herein are identical with

residues 159-206 of SEQ ID NO:66 of the copending Application. As such, the nucleic acids encoding portions of the '727 application or the publication anticipate the claims recited herein.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 33, 43 and 47-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Tjian et al (U.S. Patent No. 5,534,410, issued July 9, 1996.

Tjian et al teach nucleic acid (SEQ ID NO:1) encoding the polypeptide TAF of SEQ ID NO:2. Tjian et al contemplate nucleic acids encoding "portions of TAF's" (see paragraph bridging columns 5-6). Tjian et al contemplate monoclonal antibodies against TAF epitopes. Residues 178-186 af SEQ ID NO:2 are identical to residues 249-257 of SEQ ID NO:56 as claimed herein. Tjian et al teach nucleic acids fused to heterologous sequences and wherein the heterologous sequences encode heterologous polypeptides, vectors, host cells and methods of production and methods of making the vectors and host

cells (see columns 6-8). The nucleic acid encoding portions of the TAF of SEQ ID NO:2 of Tjian et al, vectors, host cells, methods of making the vector and host cell are therefore anticipated the disclosure of Tjian et al.

Status of Claims

Claims 18 and 19 remain withdrawn from consideration as they depend on claims that are not allowable. All claims stand rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-F 6:30 pm - 3:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Pat A. Duffy

Patricia A. Duffy

Primary Examiner

Art Unit 1645